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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/894,733	08/27/97	GENTILE M	970845

HM42/0327

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EXAMINER	
SPIVACK, P	

ART UNIT	PAPER NUMBER
1614	3

DATE MAILED: 03/27/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/894,733	Applicant(s) Gentile et al.
	Examiner Phyllis G. Spivack	Group Art Unit 1614

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-10 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892 - both copies mailed but X1 reference in on 1449 - Ps

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

Applicants are urged to file an Information Disclosure Statement if there are references deemed pertinent to the prosecution of the present application.

Claims 1-10 are under consideration.

The disclosure is objected to for the following informalities: The recitation in claim 1 "characterized by the fact that it contains" may more properly be stated as simply "comprising". The term "property" on line 3 should be plural. Appropriate correction is suggested.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bosone et al., WO 94/20449.

Bosone teaches pharmaceutical compositions suitable for parenteral administration, having anti-inflammatory and analgesic properties, wherein an alkylammonium salt of the 2-arylpropionic acid, ketoprofen, in racemic as well as enantiomeric form, is disclosed. Salts with an achiral or chiral organic base, such as lysine, dropropizine and tromethamine, are depicted. See, in particular, Examples 1-3 and 5-8. Further, a process for the preparation of pharmaceutical compositions is disclosed on pages 9-10. The claims differ in that 2-arylpropionic acid compounds other than ketoprofen, such as ibuprofen, naproxen and tiaprofenic acid, are not

disclosed. Further, Bosone does not specifically state an osmolarity range, a pH range, the absence of preservatives and supporting substances nor a requirement for a gas-inert atmosphere. However, one having ordinary skill in the art would have been motivated to prepare pharmaceutical compositions suitable for parenteral administration, having anti-inflammatory and analgesic properties, comprising 2-arylpropionic acid compounds other than ketoprofen, in view of the teachings of Bosone. Such modification would have been obvious in the absence of evidence to the contrary because ketoprofen, ibuprofen, naproxen and tiaprofenic acid are all well established in the art as 2-arylpropionic acid compounds of very close structural similarity and pharmacological activity. It would have been reasonable to expect these recited compounds to exhibit the same physical and chemical properties in a pharmaceutical composition. Further, the selections of optimal conditions for the preparation of pharmaceutical compositions with respect to atmosphere, the pH, the osmolarity and the presence or absence of excipients as preservatives and supporting substances, are parameters well within the purview of those skilled in the art of formulation chemistry through no more than routine experimentation.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number (703) 308-4703.

Phyllis Spivack

March 24, 1998

PHYLLIS SPIVACK
PRIMARY EXAMINER